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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,617	12/11/2003	Ming-qun Xu	NEB-214-US	9524
28986	7590	11/21/2005	EXAMINER	
HARRIET M. STRIMPEL; NEW ENGLAND BIOLABS, INC. 240 COUNTY ROAD IPSWICH, MA 01938-2723			VENC, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/733,617

Applicant(s)

XU ET AL.

Examiner

David J. Venci

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 29, 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 9-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on December 11, 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges Applicants' reply, filed August 29, 2005, which amended claims 1 and 5-7, and added new claim 32. Currently, claims 1-8 and 32 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-8 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, step (a), the passive voice recitation "a carrier or a ligand is fused" is indefinite because the identity of object(s) and/or step(s), if any, required for performing fusion is/are not clear.

In claim 1, step (a), the passive voice recitation "the intein is cleaved" is indefinite because the identity of object(s) and/or step(s), if any, required for performing cleavage is/are not clear.

In claim 1, step (a), the recitation of "the conjugate" lacks antecedent basis.

In claim 1, step (a), the recitation of the infinitive "to form" is indefinite. Whether the act or process of forming or formation is completed or performed, or merely intended, is not clear.

In claim 1, step (a), the adjective and/or adverbial object of the prepositional phrase "by means of a thioester-nucleophile reaction" is not clear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Muir et al. (US 6,875,594).

Muir et al. describe a method for purifying a ligand-binding molecule (see col. 24, line 27, " σ^{70} or σ^{70} derivative"; see col. 32, line 28, "specific antibodies") from a mixture (see col. 32, line 23, "human plasma") comprising the steps of: forming a carrier-ligand conjugate by intein-mediated ligation (see Abstract, "cleaving a recombinantly expressed protein from an intein and ligating the protein to a peptide"), wherein a carrier is fused to an intein (see col. 23, line 30, " σ fusion to intein-CBD") and the intein is cleaved (see Abstract, "cleaving a recombinantly expressed protein from an intein"; see col. 24, line 10+, "Protein Ligation") resulting in a C-terminal thioester (see Abstract, "forming a C-terminal thioester"); contacting the carrier-ligand conjugate with a mixture containing the ligand-binding molecule (see col. 32, line 23, "human plasma"; see col. 24, line 26, " Ni^{2+} -NTA agarose"; see col. 24, line 28, " AsiA_{His} "), selectively binding the ligand-binding molecule (see Title, "protein-capture"), and eluting the ligand-binding molecule (see col. 24, lines 33-34, "100 mM imidazole").

With respect to claim 32, Muir et al. describe a method further comprising the step of binding the carrier (see col. 23, line 30, " σ fusion to intein-CBD") to a matrix (see col. 23, line 49, "chitin column").

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Response to Arguments

In prior Office Action, claims 1 and 3-7 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Specifically, the recitation of "carrier" or "matrix-binding molecule" or "matrix-binding protein" or the various chemical-binding domains listed in claim 4 was considered indefinite because the specification did not appear to provide concise definitions for any of these terms. Applicants' claim amendments and argumentation are fully persuasive and sufficient to overcome this rejection. Accordingly, this rejection is withdrawn. Examiner's objection to the Specification in prior Office Action is withdrawn.

In prior Office Action, claims 1-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US 6,365,418) in view of Kent et al. (US 6,307,018). In response, Applicants amend independent claim 1 to add a step of "intein-mediated ligation wherein one of a carrier or a ligand is fused to an intein and the intein is cleaved resulting in a C-terminal thioester". This rejection is withdrawn in light of Applicants' amendment, and in light of new rejection under 35 U.S.C. 102(e) in view of Muir et al. (US 6,875,594), set forth *supra*.

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Conclusion

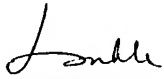
No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/14/05